



This document provides an overview of A&D SeCUR (A&D Safe, Electronic Controlling Utility for Recording).

Contents

1. What is A&D SeCUR?
2. What is FDA 21 CFR Part 11?
3. What is Data Integrity?
4. Weighing
5. Audit Trail
6. Block Diagram of Operation

1. What is A&D SeCUR?

A&D SeCUR is Windows-based software designed to collect and manage weighing data from electronic balances in compliance with FDA 21 CFR Part 11 (Title 21 of the Code of Federal Regulations, Part 11, issued by the U.S. Food and Drug Administration) and data integrity requirements.

It supports only **one A&D electronic balance** connected to the PC where the software is installed. Devices from other manufacturers or other types of measuring or analytical instruments are not supported.

For details on installation, main functions, and administrator features, please refer to the following guides:

- **A&D SeCUR Installation Guide**
- **A&D SeCUR Operator Guide**
- **A&D SeCUR Administrator Guide**

2. What is FDA 21 CFR Part 11?

This is a regulation established by the U.S. FDA in 1997, defining the criteria under which electronic records are considered trustworthy and equivalent to paper records. The main requirements and A&D SeCUR's compliance are as follows:

Main Requirements of Part 11	A&D SeCUR Compliance
Computerized system validation	Must be conducted separately by the user
Accurate and complete copies of electronic records	All data can be displayed and output in a human- and machine-readable format
Protection of electronic records	No function to delete saved data; tampering is prevented/detected via MD5 checksum and encryption
Access restricted to authorized individuals	Login requires user ID and password; accounts are managed with admin privileges
Audit trail	All operations are saved with date, time and operator name; cannot be deleted or overwritten; encrypted to prevent tampering
Electronic signature methods and management	Not supported (PDF files can be signed using external software)

3. What is Data Integrity?

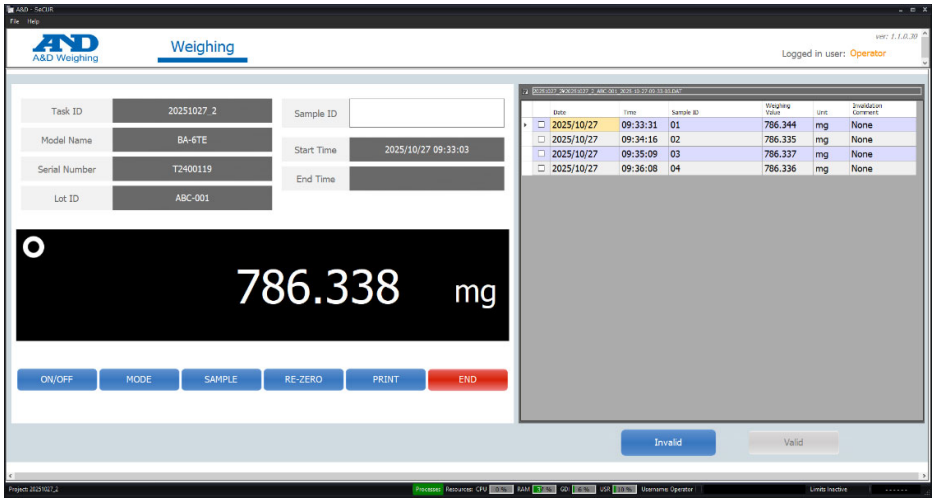
Data integrity means that data is complete, consistent, and accurate. It must comply with the “ALCOA+ Principles.” The principles and A&D SeCUR’s compliance are as follows:

ALCOA+ Principle	A&D SeCUR Compliance
Attributable	All weighing results include metadata (date, time, user name, lot name, balance info, etc.)
Legible	Data is electronically represented and organized in a tabular format for display and PDF output.
Contemporaneous	Data is saved with metadata at the time of measurement
Original	Results saved with metadata are protected from tampering via MD5 checksum and encryption; invalidated results are retained with reasons
Accurate	Accuracy is ensured through sensitivity adjustment of the balance; results are saved; software operation is guaranteed by conducting a separate computerized system validation (CSV)
Complete	All weighing results and PDF outputs include metadata; all operations including weighing tasks are saved in the audit trail
Consistent	Results are saved in chronological order in a fixed format; all setting changes are recorded in the audit trail
Enduring	Saved data cannot be deleted via the software; backups are possible
Available	Results are saved in folders by task ID, with filenames like “TaskID_LotID_Date” for easy search; audit trails can be filtered by date, operator, or lot ID.

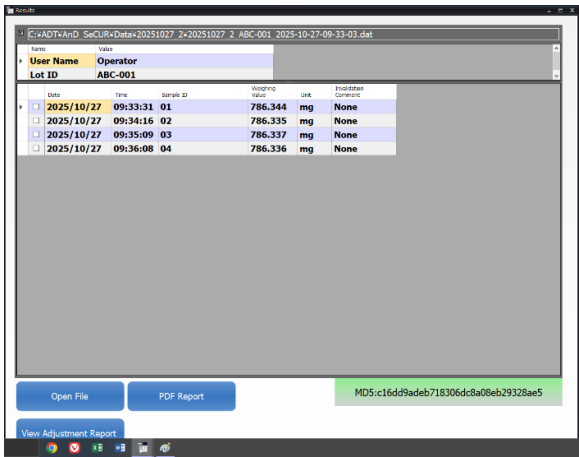
4. Weighing

Weighing data from the connected electronic balance is saved along with metadata. The saved data can be viewed or output as a PDF report.

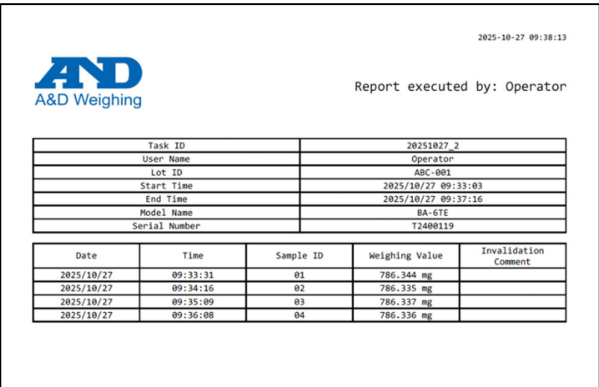
Weighing screen



Results screen



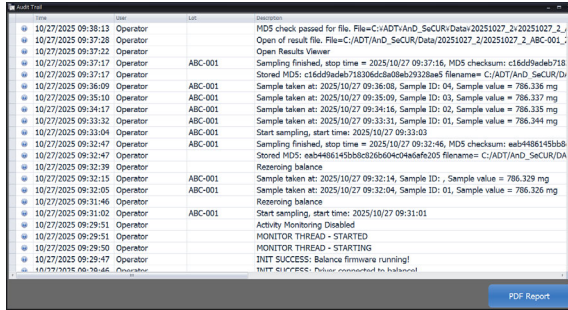
PDF report



5. Audit Trail

All operations from launching to exiting A&D SeCUR, including weighing tasks, are recorded. When logged in with administrator privileges, the audit trail can be viewed or output as a PDF report.

Audit trail screen

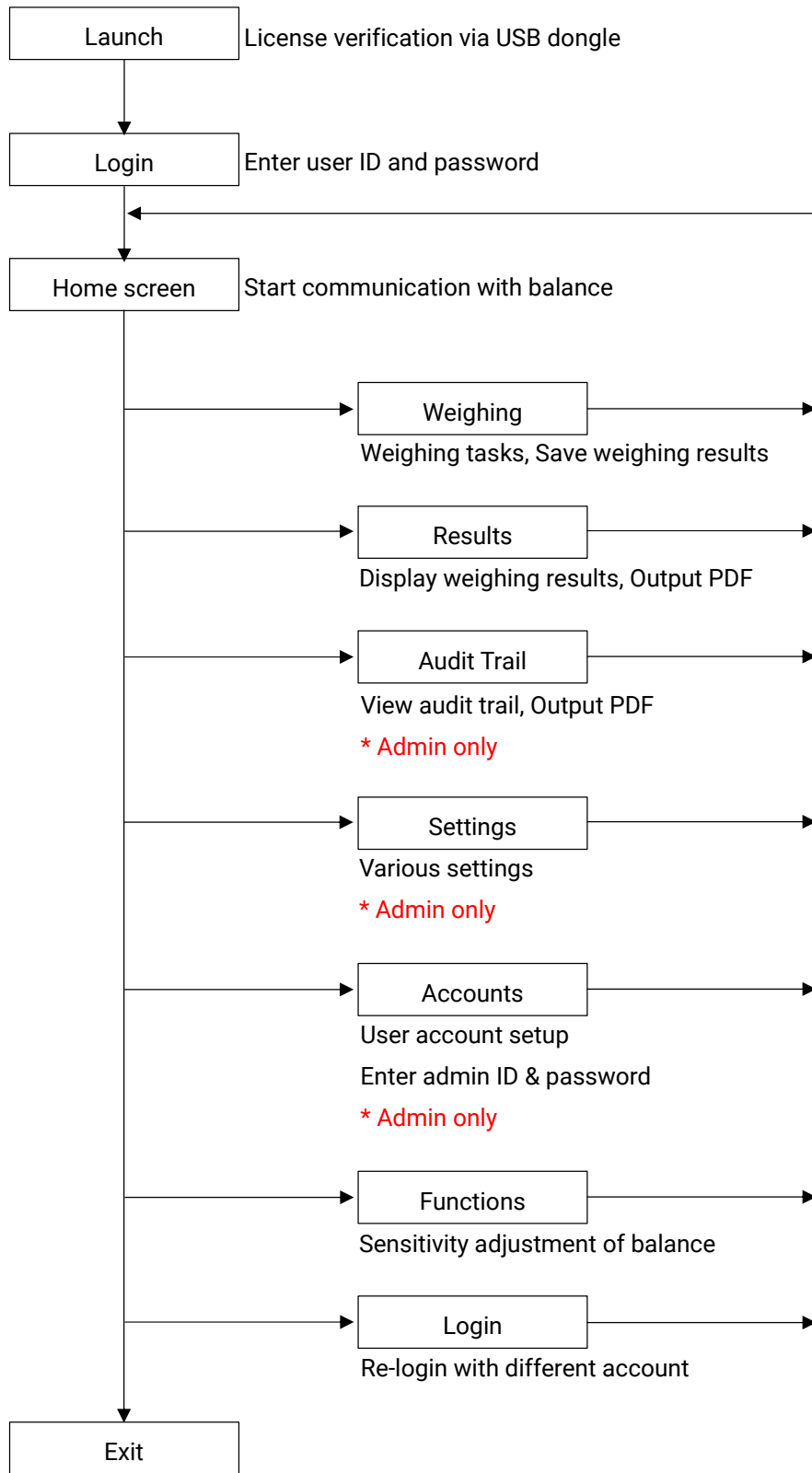


Date-Time	User	Lot ID	Operation
10/27/2025 09:38:13	Operator		MDS check passed for file. File=C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_
10/27/2025 09:37:28	Operator		Open of result file. File=C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_
10/27/2025 09:37:22	Operator		Open Results Viewer
10/27/2025 09:37:17	Operator	ABC-001	Sampling finished, stop time = 2025/10/27 09:37:16, MDS checksum: c16d9adeb718306ddc8a80eb29328ae5
10/27/2025 09:37:17	Operator		Stored MDS: c16d9adeb718306ddc8a80eb29328ae5 filename= C:\ADT\AnD_SecUR\DA
10/27/2025 09:36:09	Operator	ABC-001	Sample taken at: 2025/10/27 09:36:08, Sample ID: 04, Sample value = 786.336 mg
10/27/2025 09:35:10	Operator	ABC-001	Sample taken at: 2025/10/27 09:35:09, Sample ID: 03, Sample value = 786.337 mg
10/27/2025 09:34:17	Operator	ABC-001	Sample taken at: 2025/10/27 09:34:16, Sample ID: 02, Sample value = 786.335 mg
10/27/2025 09:33:32	Operator	ABC-001	Sample taken at: 2025/10/27 09:33:31, Sample ID: 01, Sample value = 786.344 mg
10/27/2025 09:33:04	Operator	ABC-001	Start sampling, start time: 2025/10/27 09:33:03
10/27/2025 09:32:47	Operator	ABC-001	Sampling finished, stop time = 2025/10/27 09:32:46, MDS checksum: eab4486145b8c826b604c04dafe205
10/27/2025 09:32:47	Operator		Stored MDS: eab4486145b8c826b604c04dafe205 filename= C:\ADT\AnD_SecUR\DA
10/27/2025 09:32:39	Operator		Reservoiring balance
10/27/2025 09:32:15	Operator	ABC-001	Sample taken at: 2025/10/27 09:32:14, Sample ID: , Sample value = 786.329 mg
10/27/2025 09:32:05	Operator	ABC-001	Sample taken at: 2025/10/27 09:32:04, Sample ID: 01, Sample value = 786.326 mg
10/27/2025 09:31:46	Operator		Reservoiring balance
10/27/2025 09:31:02	Operator	ABC-001	Start sampling, start time: 2025/10/27 09:31:01
10/27/2025 09:29:51	Operator		Activity Monitoring Disabled
10/27/2025 09:29:51	Operator		MONITOR THREAD - STARTED
10/27/2025 09:29:50	Operator		MONITOR THREAD - STARTING
10/27/2025 09:29:47	Operator		INIT SUCCESS: Balance firmware running!
10/27/2025 09:29:46	Operator		INIT SUCCESS: Please connect to the balance!

PDF report

Date-Time	User	Lot ID	Audit Trail Entry
10/27/2025 9:38:09 AM	Administrator		Open Audit Trail
10/27/2025 9:39:57 AM			Login success for Administrator
10/27/2025 9:38:15 AM	Operator		PDF report created: C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_ABC-001_2025-10-27-09-33-03.PDF, MDS checksum: 1043de458870c8f555be709f4669f166
10/27/2025 9:38:13 AM	Operator		MDS check passed for file. File=C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_ABC-001_2025-10-27-09-33-03.dat MDS = c16d9adeb718306ddc8a80eb29328ae5
10/27/2025 9:37:28 AM	Operator		Open of result file. File=C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_ABC-001_2025-10-27-09-33-03.dat MDS = c16d9adeb718306ddc8a80eb29328ae5
10/27/2025 9:37:22 AM	Operator		Open Results Viewer
10/27/2025 9:37:17 AM	Operator	ABC-001	Sampling finished, stop time = 2025/10/27 09:37:16, MDS checksum: c16d9adeb718306ddc8a80eb29328ae5
10/27/2025 9:37:17 AM	Operator		Stored MDS: c16d9adeb718306ddc8a80eb29328ae5 filename= C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_ABC-001_2025-10-27-09-33-03.DAT key= 6307ec57-0460-4737-bcf8-8c699746d109
10/27/2025 9:36:09 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:36:08, Sample ID: 04, Sample value = 786.336 mg
10/27/2025 9:35:10 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:35:09, Sample ID: 03, Sample value = 786.337 mg
10/27/2025 9:34:17 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:34:16, Sample ID: 02, Sample value = 786.335 mg
10/27/2025 9:33:32 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:33:31, Sample ID: 01, Sample value = 786.344 mg
10/27/2025 9:33:04 AM	Operator	ABC-001	Start sampling, start time: 2025/10/27 09:33:03
10/27/2025 9:32:47 AM	Operator	ABC-001	Sampling finished, stop time = 2025/10/27 09:32:46, MDS checksum: eab4486145b8c826b604c04dafe205
10/27/2025 9:32:47 AM	Operator		Stored MDS: eab4486145b8c826b604c04dafe205 filename= C:\ADT\AnD_SecUR\Data\20251027_2\20251027_2_ABC-001_2025-10-27-09-33-01.DAT key= 206679cc-ba53-402e-bf84-505a5a954974
10/27/2025 9:32:39 AM	Operator		Reservoiring balance
10/27/2025 9:32:15 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:32:14, Sample ID: , Sample value = 786.329 mg
10/27/2025 9:32:05 AM	Operator	ABC-001	Sample taken at: 2025/10/27 09:32:04, Sample ID: 01, Sample value = 786.326 mg
10/27/2025 9:31:46 AM	Operator		Reservoiring balance
10/27/2025 9:31:02 AM	Operator	ABC-001	Start sampling, start time: 2025/10/27 09:31:01

6. Block Diagram of Operation



End